IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S COUNTER DEPOSITION DESIGNATIONS OF JANICE CONNOR TAKEN 3/11/15 AND 4/21/15

BSC Counter Designation	Objection	Plaintiffs Counter Designation to BSC Counter Designation
jc031115, (Pages 149:8 to 150:2) **149** **8 Q. Okay. So has Boston Scientific** **9 undertaken to look at the mesh that has been** **10 removed due to complications to see whether** **11 degradation was present or was clinically** **12 significant in those particular cases?** **13 A. So Boston Scientific has not done a** **14 study to remove mesh out of women, because we** **15 don't believe that that event is occurring.** **16 Q. So you don't -- you haven't reviewed** **17 it under a scanning electron microscopy because** **18 you don't think that it happens, right? You**		***[Plaintiffs Counter to 149:8-150:2]*** **150:3-7** ***3 Q. Well, it's certainly not performing*** ***4 appropriately for the women who have had to have*** ***5 it removed, correct?*** ***6 A. I don't know enough about all those*** ***7 cases to comment.***

19 don't think that that's something that needs to **20 be studied?** **21 A. So based on the information we have on** **22 our products, we believe that the product is** **23 performing acceptably, so we don't -- we aren't** **24 conducting a study to then take the mesh out of** **25 the women to see how it's performing because we** **150** **1 know based on the clinical evidence that it's** **2 performing appropriately.**		
jc031115, (Page 151:1 to 151:16) **151** **1 Q. Okay. So you have not looked for** **2 degradation under any kind of microscopy or** **3 anything like that, correct?** **4 A. So again, no, we have not done that** **5 because we don't believe that it is necessary.** **6 Q. Why not? How are you so sure you're** **7 right?** **8 A. Because it's based on the clinical** **9 evidence. So if mesh were to fall apart, you** **10 would see it in these studies. These studies** **11 have high success rates. So if mesh were to** **12 fall apart in a woman, there would be a clinical** **13 effect as such in that report. So we review** **14 this literature, same as other products, to look** **15 for evidence that the mesh is not performing** **16 appropriately.**		**[Plainitffs Counter to 151:1-151:16]** ***jc031115, (Pages 154:19 to 155:6)*** ***154*** ***19 Q. Okay. So for those women who have had*** ***20 mesh removal surgery for complications,*** ***21 something has gone wrong with the mesh, correct?*** ***22 A. Typically there's a reason why it's*** ***23 removed, yes.*** ***24 MR. ANIELAK: Form.*** ***25 BY MS. FITZPATRICK:*** ***155*** ***1 Q. Boston Scientific has not undertaken*** ***2 any kind of studies to determine if it was*** ***3 degradation that happened to the mesh that led*** ***4 to the complications in those women, correct?*** ***5 A. So Boston Scientific has not done a*** ***6 specific mesh explanted study on women.***
jc042115, (Page 432:11 to 432:22) **432** **11 Q. Good morning.** **12 A. Good morning.** **13 Q. Please tell the jury your name and**	**432:11-432:22** **FRE 403, Duplicative**	

14 introduce yourself. 15 A. My name is Janice Connor. 16 Q. And, where do you work? 17 A. I work at Boston Scientific. 18 Q. And, what do you do there, just 19 generally? 20 A. I'm the Director of Clinical 21 Programs for the Urology and Women's Health 22 Division.		
jc042115, (Pages 436:25 to 439:18) 436 25 Q. Okay. I now want to talk about 437 1 Boston Scientific's devices that it has marketed 2 for the treatment of pelvic organ prolapse, the 3 Pinnacle and Uphold devices. 4 Did Boston Scientific conduct 5 clinical trials in women specifically with those 6 two devices prior to going to market? 7 A. No. 8 Q. Why not? 9 A. No. For, actually, both of those 10 devices, they're made from Polyform. So, it's, 11 again, a type one macroporous monofilament 12 polypropylene mesh used to treat pelvic organ 13 prolapse. 14 That product was already on the 15 market prior to Pinnacle and Uphold being placed 16 on the market. So, again, we had not -- Pinnacle 17 and Uphold weren't new products. They were 18 basically a package of a product put in a 19 different shape and placed on the market of a 20 product that was already on the market. 21 Two products, the Capio, the 22 delivery system, and the mesh. So, again, we 23 didn't create a new product. We basically put 24 them together in a different package and then 25 marketed it that way. 438 1 So, we didn't -- I'm sorry. I think 2 your question was why didn't we run studies. 3 We had the Polyform mesh and we were	436:25-439:18 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

4 able to use data from that mesh, human data, to 5 understand how that mesh was working. 6 Q. And, did Boston Scientific consider 7 data from similar devices used to treat pelvic 8 organ prolapse when assessing whether a clinical 9 trial was necessary prior to going to market? 10 A. Yes. So, Uphold and Pinnacle were 11 marketed, I believe, in 2008 and 9 and there were 12 already meshes on the market prior to those dates 13 for pelvic organ prolapse that we could review 14 and use that human data. 15 Q. And, have clinical studies been 16 conducted on Uphold and Pinnacle since those 17 products have been marketed? 18 A. Yes. 19 Q. And, has Boston Scientific funded 20 those studies? 21 A. We have funded studies and there are 22 also other studies managed by physicians with no 23 request for funding. 24 Q. And, generally, what do the overall 25 body of studies show with regard to the Pinnacle 439 1 and Uphold devices? 2 A. Overall it shows that the products 3 are safe and that they're effective. So, 4 overall, the safety, again, looking at the 5 complications. So, how do the patients feel, 6 what events have they experienced, have they had 7 any pain or any other complications occurred. 8 Those events that have occurred in 9 women are similar to events that occur for 10 surgery for POP without a device and also similar 11 to other devices. 12 So, we show that overall the product 13 is safe. And, again, overall the product's 14 working. So, the symptoms that the patients 15 experienced, bulging, issues with urine 16 frequency, issues with bowel, issues or		

17 dysfunction with sexual functioning, those have 18 been improved.		
jc042115, (Pages 439:24 to 441:15) 439 24 Tell the jury a little about your 25 background before coming to Boston Scientific. 440 1 A. Before coming to Boston Scientific 2 from my -- sorry. For my educational background, 3 I have a bachelor's in science from the 4 University of Massachusetts. University of 5 Massachusetts at Amherst. 6 And, I also have a graduate degree 7 from the Massachusetts College of Pharmacy in 8 health sciences from 2003. 9 And, then, from my career 10 standpoint -- those are my two educational 11 backgrounds. 12 And then from a career standpoint, 13 after college I began working at Harvard Medical 14 School in Massachusetts. 15 And then I went to Beth Israel 16 Deaconess Medical Center for a couple of years 17 working on the administrative aspect of clinical 18 research with the hospital. 19 And then I took a position as a 20 project manager at Stryker Biotech, which is a 21 medical device company for bone implants. And I 22 worked there for almost five years. 23 And then I started working at Boston 24 Scientific in 2004, beginning in their endoscopy 25 department where I managed clinical studies on 441 1 devices for gastrointestinal blockages, 2 basically. 3 And then I started working in 2009 4 for the urology and women's health division. 5 Q. Very good. 6 Do you also have any teaching or	439:24-441:15 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

7 faculty positions or have you ever done that over 8 the years? 9 A. I do. So, recently I was awarded a 10 faculty position at the University of 11 Massachusetts at the Worcester Medical School. 12 So, I was part of the department of family 13 medicine and community health. So, I'm running a 14 program there to teach the fellows on medical 15 technology.		
jc042115, (Pages 441:16 to 442:3) 441 16 Q. Okay. And, in terms of your current 17 position. 18 What is your current title? 19 A. I'm the Director of Clinical 20 Programs for Urology Women's Health Division. 21 Q. Okay. And, when did you become 22 involved with the women's health division as 23 opposed to the endoscopy division which is where 24 you started at Boston Scientific? 25 A. 2009. 442 1 Q. Okay. So, total, how long have you 2 been working in the area of clinical research? 3 A. It's over 20 years.	441:16-442:3 FRE 403, Duplicative	
jc042115, (Pages 442:4 to 447:23) 442 4 Q. I want to talk a little bit about 5 Boston Scientific and where the clinical 6 department fits in. 7 Describe for the jury where the 8 clinical department fits into the overall scheme 9 of Boston Scientific and the other departments 10 that work in women's health? 11 A. There are multiple departments. So, 12 what we're looking at is just an example of the 13 different departments that are involved in 14 product development. And also monitoring product 15 safety within Boston Scientific. 16 So, this is illustrating how there 17 are multiple departments in the urology women's 18 health division. Clinical is included in there.	442:4-447:23 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

And our main responsibility is to support the activity around clinical research. So, what that means is we provide input to the other functions on clinical trial design, significance, interpretation of results, and we manage any clinical studies that Boston Scientific sponsors. We oversee clinical studies 443 that Boston Scientific funds, and we also have input into the risk management process of Boston Scientific. And that is through the clinical literature. Q. Specifically on research and development. How does the clinical group then interact with that process in bringing a product to market? A. The research and development department has different responsibilities. One of them is to develop new products. If the research and development was creating a new clinical or a new medical product for use in the human body, the clinical department would be involved in terms of providing feedback on clinical study design, what types of studies would give the answers to the questions that the department might have on the product, how it might act in the human body, what other literature is available on similar products. Q. So, in terms of looking at literature that exists on similar products that 444 are on the market during the R&D phase, how does the clinical department go about providing that input? A. The clinical department reviews the literature. So, we have certain terms that we will search for in literature databases and get		

an output of all the literature that meets that criteria. And then search through the literature to find the studies, data, review articles that provide information about the therapy, alternative treatments, competing treatments, safety effectiveness on that device or similar devices. Q. So, would the clinical department then provide the input for the Advantage and the Obtryx about the clinical literature and the studies that have been done on similar products prior to those products going to market? A. Correct. Q. And, would that same process exist or did that same process happen with regard to Pinnacle and Uphold in terms of the clinical department giving input as to what human studies had been done with mesh to treat pelvic organ prolapse? 445 A. Yes. Q. I want to talk a little bit about what you do as the clinical director. What are some of your primary responsibilities personally? A. Some of my primary responsibilities, obviously, center around clinical studies. So, primarily, myself, I manage the sponsor clinical studies. So, I have a team that I oversee that manages the clinical studies, works with the outside physicians on the activity involved in those clinical studies. So, that's probably the primary responsibility. Secondarily, I will monitor the research grants. So, the research grants are proposals from outside physicians where they're looking for funding or support from Boston Scientific on running a clinical trial. Boston Scientific doesn't manage the study. We just ask for updates from that physician. So, that's also part of my responsibility.		

I also will work with the different departments, specifically R&D or marketing or other departments on clinical strategy, understanding what their needs are, what their

446

questions are, especially from the physicians as well.

And, on top of that, from dealing with the physicians, I do also have a responsibility to attend the medical society conferences. And, at those conferences we learn a lot about what science is happening, what research is being conducted, what new information is being learned or what some of the outstanding questions are.

Q. So, in terms of getting input from physicians about Boston Scientific's products, do you receive that input from physicians?

A. Myself and other departments do as well.

Q. And, how do you receive input from physicians about our devices? Explain to the jury how that happens.

A. Through the clinical trials is one example. So, any of the trials we run or the trials that we support, we do receive feedback from the physicians on the information they're collecting.

Q. And, then, in terms of your interacting with physicians, how do you receive

447

input from physicians through that process in terms of attending medical meetings or sitting down with physicians and getting their input?

A. Correct. So, again, one of my main responsibilities is to work with the outside physicians. So, at medical society meetings I will meet with the physicians, sit with them to ask questions about their studies they're running, what are they learning, if they believe

other -- what other research is necessary to go to their presentations and meet with them after, again to ask them more questions there. Also, I will meet with them in their office. So, I'll visit the hospitals or clinics and meet with the physician there to basically see their practice and speak with others on their staff to learn about their use of our products, other products, and answer some questions. Q. And, have you been engaging in that kind of dialogue with outside physicians about Boston Scientific slings and devices to treat pelvic organ prolapse? A. Yes.		
jc042115, (Pages 450:3 to 451:11) 450 Q. And, has Boston Scientific funded and supported clinical trials of the Uphold device? A. Yes. Q. And, generally, explain how that happens. How does Boston Scientific fund and support research into medical devices? A. There is two different ways. One way is if Boston Scientific sponsors that research project. And that means that Boston Scientific, along with a physician, has that scientific question, develops that study protocol, develops what assessments that will be undertaken by the patient to answer those questions. The sponsored study is when Boston Scientific has the responsibility over the study, over the conduct of the study. We don't treat patients. The physicians treat patients. We don't see the patients in the office. The physicians see the patients. We're just responsible for ensuring the physicians are conducting the study and we understand the 451 information. The other way that we get involved in clinical studies is by the research grants.	450:3-451:11 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

4 And they're also -- another name for that is 5 investigator sponsored research studies or ISRs. 6 Same term. 7 This is when physicians will request 8 support from Boston Scientific, either through 9 funding, dollars, or product and basically are 10 looking for that assistance in conducting that 11 research study.		
jc042115, (Pages 451:13 to 452:10) 451 13 When looking at what Boston 14 Scientific studies, the company has either funded 15 or supported, it would include both the sponsored 16 research and the ISR studies; is that right? 17 A. That's correct. 18 Q. And, then, tell the jury what an 19 independent study is. What does that mean? 20 A. An independent study is a study that 21 doesn't meet any of the other two criteria, 22 basically. It is a study that physicians run on 23 their own in their practice and they don't 24 require or request any support from Boston 25 Scientific. 452 1 Q. What are the main differences 2 between the Boston Scientific sponsored or the 3 investigator sponsored? 4 A. You know, there are more 5 similarities than differences. 6 So, these are still studies where 7 physicians are treating the patients. They're 8 collecting the data. They're asking the 9 questions. They're giving their input on the 10 data.	451:13-452:10 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jc042115, (Pages 452:13 to 453:10) 452 13 The difference is on who has overall 14 the responsibility over the conduct of a study. 15 And that basically means if there was a time 16 where the study results had to be reported to an 17 agency or another company, who has that 18 responsibility to write that report. That's the 19 main difference. 20 For a sponsored study, it's Boston 21 Scientific who has that responsibility. For an 22 investigator sponsored research study, it's the 23 investigator who has that responsibility.	452:13-453:10 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter	Plaintiffs adopt and incorporate their counter designations, if any.

24 Q. When looking at the literature on 25 Boston Scientific studies, would it be 453 1 appropriate to just dismiss out of hand any of 2 these kinds of studies? 3 A. No. So, again, when I said -- so, 4 there is more similarities than differences. 5 These are still patients being treated in a 6 hospital setting by a physician. And, the data 7 are still collected the same way and reported. 8 If you only looked at one, you'd be missing out 9 on important data from the other studies and vice 10 versa.	designations, if any.	
jc042115, (Pages 454:20 to 456:12) 454 20 Okay. And, I know you went into it 21 a little bit, but I want to talk about the ISR 22 program and the R&E committee, the committee that 23 examines some of these ISR requests. 24 Explain to the jury what the R&E 25 committee is and how it does its job. 455 1 A. The R&E committee is a -- it stands 2 for the research and education committee. Is a 3 committee made up of different departments in the 4 division. For example, the research and 5 development department, the regulatory 6 department, medical, clinical. 7 And these different departments give 8 feedback on research grants when they're 9 submitted. So, these -- there is, for example, 10 from a medical standpoint, the medical director, 11 who is the medical representative on this 12 committee, reviews a research proposal from a 13 physician and comments on the study design, will 14 it answer the questions that are asked. Is there 15 enough -- are there enough patients proposed to 16 be followed in this study that will give that 17 answer. Has this physician conducted research 18 before, are they qualified to conduct research.	454:20-456:12 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

19 Is there a safety plan in place. 20 So, each different person 21 representing their department is part of this 22 committee and looks overall at the proposal from 23 the physicians. 24 Q. Is the research and grant committee, 25 is that similar to other organizations that 456 1 have -- that fund clinical research? 2 A. It is. So, many corporations 3 outside of the company have a similar program. 4 So, there are -- definitely, it's just part of 5 connecting research for companies who will have 6 research that they directly manage, which is the 7 sponsored piece of the puzzle, and there is also 8 research that they fund. 9 And, there is actually many 10 different larger, Stanford, for example, Mayo 11 Clinic, big hospitals that have direct input into 12 research committees for future proposals.		
jc042115, (Pages 458:25 to 460:11) 458 25 Q. So, in terms of getting safety 459 1 information from clinical trials. How does that 2 information make its way from the woman to the 3 doctor, but how does it make it then from the 4 doctor to Boston Scientific? 5 A. The doctor will -- if there is a 6 safety event, let's say there is a report of 7 pain. 8 That report directly gets entered by 9 the physician or somebody on his or her staff 10 into that database. We have a safety trial 11 manager, a person on my staff, who has the 12 responsibility to daily look for those 13 complications. That information is then 14 collected. There is a process internally where 15 the medical director reviews reports, and we 16 analyze that data. So, it's an automatic output 17 from that database to somebody on the clinical 18 staff.	458:25-460:11 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

19 Q. And, then, in terms of how 20 physicians are then made aware of the results of 21 clinical research, how does that happen? Explain 22 that process. 23 A. They're published, basically. So, 24 overall, when these studies are run, whether 25 they're sponsored or funded, the physician has an 460 1 obligation in the company to make the results 2 public. So, there is different ways these 3 results can be presented at a medical society. 4 And whether it's in a format where the physician 5 stands at a podium and talks about the data or 6 it's in a format where the data are printed on a 7 large poster and placed in an exhibit hall with 8 other posters of scientific studies. Or the 9 study results are published in a manuscript. So, 10 it's in a medical journal where that study is 11 printed, basically.		
jc042115, (Pages 460:24 to 461:9) 460 24 Q. With regard to the Uphold device. 25 Has Boston Scientific funded and supported 461 1 clinical studies of the Uphold device? 2 A. Yes. 3 Q. And, have those studies been 4 completed? 5 A. Yes. 6 Q. And, have those studies of the 7 Uphold device been presented and published to 8 physicians? 9 A. Yes.	460:24-461:9 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jc042115, (Pages 462:9 to 465:1) 462 9 (Exhibit 1328, BSC Pelvic Floor 10 Clinical Cadence, marked) 11 Q. (By Mr. Anielak) All right. I've 12 marked as Exhibit 1328 a Boston Scientific 13 document entitled BSC Pelvic Floor Clinical 14 Cadence. 15 Explain to the jury what this is. 16 A. This is a snapshot in time of the	462:9-465:1 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections	Plaintiffs adopt and incorporate their counter designations, if any.

clinical studies that were -- either there is some future trials planned, funded, sponsored from 2009 through 2012 for the pelvic floor devices. Q. So, the snapshot in time for this particular summary is in 2009; is that right? A. That's correct. Q. And, describe for the jury, just orient the jury to what the shading represents 463 and what information is presented on here because there is a lot going on. A. Yeah, it's a busy slide. So, there -- basically the trials, all the different studies are listed on that left column. And, if you follow those across to the right, there is long arrow with different colors on it. And, the different colors mean the different phases of a clinical study. And, I believe I have a little key on the bottom there. And it shows that the different shading or colors line up to different phases. So, for example, studies typically start with the enrollment phase, which mean the patients are asked to be in the clinical study. Each clinical study has a certain number of patients that they need from a statistical point of view, and that they're looking to recruit in the study. So, that's the first phase. When that phase is complete, there is typically a phase where you follow patients. So, this is when patients are followed forward in time to collect data. So, I talked about some of 464 the data that's collected. Each study has a certain time as to how long they would like these patients to be seen, as to how long after the treatment they will collect data. After that phase, typically the data are analyzed and a report is generated, which is the shading with some lines there. And, then, finally the data are	set forth in counter designations, if any.	

10 published in some format. 11 Q. So, in 2009, describe for the jury 12 what studies Boston Scientific was supporting 13 with regard to the Uphold device? 14 A. So, if I go through the list. 15 Little difficult with the shading and it's black 16 and white. 17 But there is an Uphold study by Dr. 18 Sands. There is another Uphold, it's an economic 19 study. And it's Dr. Culligan. 20 Q. On the Dr. Sands Uphold study. 21 Has that study been completed? 22 A. Yes. 23 Q. And, has that study been published 24 and presented to physicians, the results of that 25 study? 465 1 A. Yes, it has.		
jc042115, (Pages 467:3 to 468:5) 467 3 Q. Do the studies that Boston 4 Scientific has conducted -- these studies. The 5 Uphold studies, the Pinnacle studies, the Obtryx 6 studies. 7 Do they support the safety of Boston 8 Scientific's slings? 9 A. They do. 10 Q. And, explain that to the jury. 11 How do the studies support the 12 safety of Boston Scientific's slings? 13 A. So, all of these studies are asking 14 questions about safety. And, it doesn't matter 15 if they're -- how they're -- you know, what 16 questionnaires they're asking or whether the 17 study -- it's where it is in the list of 18 endpoints in the study. They're asking questions 19 about safety. 20 So, all of these studies are asking 21 the patients to report any medical complications 22 that they experience. 23 During the procedure, if the 24 physician is aware of them or the patient right 25 through until the last point that the patients 468	467:3-486:5 FRE 403	

1 are followed. They have that entire time frame 2 to report any type of medical event that has 3 occurred. 4 All of these studies on pelvic floor 5 meshes collect that safety data.		
jc042115, (Page 468:6 to 468:15) 468 6 Q. And, then, in terms of effectiveness 7 for these devices. 8 How are the studies collecting data 9 on effectiveness? 10 A. For all these studies, and typical 11 most of pelvic floor studies, they ask how the 12 product is working in two different ways. 13 Objectively, so kind of a more black and white 14 answer in terms of has the -- did the device 15 perform the way it was intended.	468:6-15 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jc042115, (Pages 468:21 to 469:4) 468 21 From a pelvic organ prolapse 22 standpoint, it asks questions about -- from 23 objectively, has that organ; bladder, the uterus, 24 the rectum, whatever part of the body it is 25 that's not in the right location, has that 469 1 improved. Is it back to where it should be. 2 So, from the objective standpoint. 3 And that could be done by the physician doing 4 tests on the patient.	468:21-469:4 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jc042115, (Pages 469:10 to 471:2) 469 10 Patients are also asked how do they 11 feel about their symptoms. So, that's a 12 subjective nature. Do they feel as if their 13 symptoms have improved, are they able to do 14 activities that they couldn't do before. 15 So, that's how we measure and how 16 these studies support the effectiveness of these 17 devices. 18 (Exhibit 1329, Women's Health 19 Clinical Program Cadence, marked) 20 Q. (By Mr. Anielak) I've marked as 21 Exhibit 1329 what appears to be a similar	469:10-471:21 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

document to the other cadence document we just looked at. But explain to the jury what this is. 470 A. It is similar. It is, again, a snapshot in time. I believe this is March, 2012, of the clinical program for the women's health products. Q. So, again, orient to the jury to how the chart is set up and what it means. A. Mm-hmm. There is different rows, basically. So, there is -- the top part here is on slings. So, it has, again, the column right to the right of the word slings, three different clinical studies that were on-going at the time of this snapshot. So, there are three different studies there. And, again, if you follow it to the right, the different colors and shading will show the different phases that I had referred to before on about -- in a clinical trial. Enrollment, follow-up, and then the finalization, the analysis, and the final report. These little stars, basically indicate at what point the data will be available to the public. And, it's a projected date. The studies, obviously, can be slower or faster depending on the study, the design, many different variables. So, that's kind of an 471 estimated time point of when the data will be available to the public.		
jc042115, (Pages 471:7 to 472:5) 471 Q. And, then, under Pinnacle there are a number of studies that are identified that were on-going in 2012? A. Yes. Q. And, this is a Pinnacle retrospective. Describe for the jury what that is? A. That was a study, I believe, started in 2010. And, Dr. Peter Rosenblatt was the	471:7-472:5 FRE 401, 402, 403 Funding post implantation studies is irrelevant to BSC's conduct in 2010.	

physician who has the main responsibility for that study. It was a study looking at data in women treated with the Pinnacle device for anterior or apical pelvic organ prolapse. And I believe there were over 200 women who were in that clinical study and data was presented on that study. Q. And, have the results of that study 472 been presented to physicians? A. Yes. Q. So, that study is completed on Pinnacle? A. Correct.		
jc042115, (Pages 472:6 to 473:19) 472 Q. There is a number of studies that were on-going in 2012 with regard to Uphold, right? A. Yes. Q. And, there is one that says Uphold retro pain. Describe for the jury what that particular study is. A. It was a comparative study in patients who were treated with the Uphold device, and then patients who were treated with native tissue. So, meaning that for pelvic organ prolapse, the physician basically used sutures, stitches with the patient's own tissue to fix that pelvic organ prolapse. So, it was a short-term study assessing the postop pain experienced from patients. Q. And, have the results of that study been presented? 473 A. Yes. Q. So, that study has been completed? A. Yes. Q. And, there is other Uphold studies identified on here. The uphold Nordic study, what study is that? A. That is a clinical study by Dr. Daniel Altman in the Nordic countries.	472:6-473:19 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

He had done a clinical study assessing data on patients treated with Uphold Lite, and they were treated out to one year. There were over 200 patients in that clinical study. Q. And, has that study been completed on Uphold? A. It has. Q. And, have the results of that study been presented? A. Yes.		
jc042115, (Pages 473:22 to 474:5) 473 Does Boston Scientific continue to fund and support research into its mesh devices? A. We do, yes. 474 Q. And, so we could look at continued cadence documents up until today that would have clinical studies on them that show Boston Scientific funding studies on its mesh devices? A. Yes, that's correct.	473:22-474:5 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jc042115, (Pages 474:9 to 475:11) 474 During the time that you've been the clinical director in the women's health division, has there always been budgets to conduct clinical trials on mesh devices? A. Yes. So, every year there is a budget to support clinical trials. Q. Explain that to the jury in terms of budgeting for clinical trials and how that works. A. Yeah. Each department has a budget. So, we had talked about the different departments within the division. So, each department has a specific budget that's approved by, you know, the executives at Boston Scientific. The clinical department has always	474:9-475:11 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

had a budget to support clinical trials. So, the way that works is that the clinical department, with feedback from other departments, will 475 propose specific trials to run or the amount of funding that is needed to support the products through clinical studies. And, that funding is obviously reviewed by executives in the company and then is either approved or there is questions are modified. But there has always been a budget there. So, since I've been with this division in 2009 there's been a clinical budget that's been in place since that time frame.		
jc042115, (Pages 475:12 to 476:19) 475 Q. You were shown an email where you were indicating that there was zero budget in the -- to conduct a certain proposal. Explain to the jury what you meant when you said there was zero budget at that particular time. A. Yeah. The way the budget works is at the beginning of the year there is a set amount in place. It's to support any activity within that department for that entire year. So, it's possible at that beginning of the year there were certain trials or activities that were already allocated for that budget. And then by July, August, September, 476 October, whatever the time frame is later in that month, there might be more requests for dollars; yet, again, the dollars that are approved in the budget are already assigned to a certain project. So, at certain times there might not be new dollars available; however, that's when you basically will request those funds for the following year or you will monitor that request the following year to understand if it is relevant at that time or not.		

11 Q. And, as the clinical director at 12 Boston Scientific, do you advocate for more money 13 for clinical trials in the clinical department? 14 A. I do. So, I'm obviously passionate 15 about my job and my responsibility. I take that 16 seriously. So, I will typically have responses 17 about budget, to always advocate for dollars 18 supporting the clinical research strategy for 19 that continuous support of funds for the years.	476:11-19 FRE 401, 402, 403	
jc042115, (Pages 476:20 to 478:20) 476 20 Q. I want to talk a little bit now 21 about study design. 22 You were asked a number of questions 23 about prospective studies and comparative studies 24 and randomized controlled studies. 25 Describe for the jury, just 477 1 generally, what study design is and what that 2 means, that term. 3 A. Study design means what type of 4 clinical trial is being conducted. So, that 5 didn't really explain it very well. 6 So, there is different ways to get 7 the answers to the questions we have. So, again, 8 if you're asking the question, how does this 9 product work in humans, and I want to know at one 10 year, how is it compared to a different product, 11 there are different ways to get that answer. 12 You can do a study called a 13 retrospective study where you're looking at 14 patients who are already treated with that 15 device. So, if you're asking for, what happens 16 at one year, you will look through your medical 17 charts, find all the patients who had that 18 procedure and either call them at one year or 19 look through to see if you have that data. And 20 that's one way to get the answer. That's a 21 retrospective design. 22 There is also something called a	476:20-478:20 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

23 prospective design, which means you're following 24 patients forward. Patients are treated today and 25 they're followed out to one year. And that's 478 1 prospectively getting the answer to your 2 questions. 3 There is also different ways to 4 compare products or therapies to get your answer. 5 And there is something called a 6 randomized controlled design, which means you're 7 typically following the patients forward, but 8 you're randomly selecting what therapy those 9 patients receive or device, pharmaceutical. 10 So, all patients are the same in 11 terms of they meet a certain criteria, but then 12 randomly, like a flip of a coin, they're assigned 13 a different treatment, and you follow them 14 forward. 15 You can do studies where you're only 16 assessing one therapy, you can do them where 17 you're comparing two, but you're not randomizing. 18 Your physicians are selecting. 19 So, there is many different ways to 20 answer the question that you're asking.		
jc042115, (Pages 478:25 to 479:4) 478 25 Q. And are there many different study 479 1 designs that have looked at Boston Scientific's 2 devices to treat pelvic organ prolapse on 3 Pinnacle and Uphold? 4 A. Yes.	478:25-479:4 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jc042115, (Pages 479:9 to 481:5) 479 9 Is a randomized controlled trial the 10 only study design that can provide scientific 11 information about how a device performs in 12 women?	479:9-481:5 BSC has previously designated this testimony.	Plaintiffs adopt and incorporate their counter designations, if any.

A. No, not all all. There are many different types. So, I mentioned a few of those. So, there is comparing products to each other by not randomizing. There is doing studies where it's just one treatment that's offered. So, it's definitely not the only way to give an answer to a question. Q. And, are there strengths and limitations to all study designs? A. There are. In a randomized study, for example, the strengths are that you try to narrow down the variables that you study, so you feel as if you get -- you get the answer. There 480 is only one reason why you get that answer, because of that medical intervention. But there is limitations. For example, in a surgical trial you can't necessarily limit all those variables because patients anatomy is different. There is not a way to absolutely know that the tissue quality in one patient is the same as the tissue quality in another. There is not a way to randomize that. There is not a way to randomize physicians surgical skills within the setting of that surgery. There is things that obviously happen in a surgery that the physician has to react to. That's not a controlled environment where you can make sure that doesn't happen. So, that's a limitation to a randomized trial where you can't rule those out. So, when you get the results, can you absolutely guarantied say that that's because of the intervention not because of maybe some of these other variables that you can't control. Q. But with all study designs, there are textbooks and classes that last all year long in college that talk about the strengths and	Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	

25 limitations of different study designs, right? 481 1 A. True. Yes. 2 Q. Not withstanding that, has Boston 3 Scientific conducted randomized controlled trials 4 on its mesh devices? 5 A. Yes.		
jc042115, (Page 481:6 to 481:13) 481 6 Q. And, are there randomized controlled 7 trials that have been conducted on Boston 8 Scientific's Advantage sling, for example? 9 A. Yes. 10 Q. And, are there randomized controlled 11 trials that have been conducted on Boston 12 Scientific's Obtryx sling for example? 13 A. Yes.	481:6-481:13 FRE 401, 402, 403	
jc042115, (Page 481:14 to 481:21) 481 14 Q. Do all of the study designs provide 15 information about the safety of the devices? 16 A. They do. All of these studies will 17 ask the question to the patient or the physician 18 on how the patient is doing. They all will 19 gather that information. So, they all report on 20 medical events that occurred in the clinical 21 setting.	481:14-21 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jc042115, (Pages 482:4 to 485:23) 482 4 Q. And, so, for those types of devices, 5 like pain or dyspareunia that may occur following 6 a placement of one of Boston Scientific's 7 devices, how do doctors assess those 8 complications and how does Boston Scientific 9 assess those complications through clinical 10 trials? 11 A. In a clinical trial -- so, for 12 example, in some of these clinical trials that we 13 have supported. 14 After the patient is treated, for 15 example, dyspareunia. The patient is asked 16 questions, has that symptom, are they able to	482:4-485:23 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

engage in sexual activity, better, different, has any symptoms occurred, is it better, improved since before they had the treatment. So the physicians ask the question to the patients, the patients provide the feedback. And, again, that information is collected in the study summarized and basically presented in the final results. Q. And, then, in terms of how 483 frequently complications occur in a clinical trial. How is that information gathered and then presented and made known to Boston Scientific in terms of how frequently something like pain might result following a placement of one of Boston Scientific's mesh devices? A. For example, for a certain medical event that the company, the physician, others had questions about, you gather information on the rate by finding out how many patients had the event, and then how many patients, in total, were treated. So, for example, if a study enrolled -- there were 100 women who had the procedure, and you asked the question of how many of that sample size; the 100 women, had reported that event, and there is 10. Then, basically, it's 10/100 women, which is a rate of 10%. Q. Okay. And, so, are the rates of complications like pain, are they presented in clinical trials? A. Yes. Q. And, have those types of 484 complications like pain. Have rates of pain been presented and looked at in Boston Scientific's clinical trials of its mesh devices? A. Yes.		

Q. You were asked a couple of questions about study endpoints. And, without getting too much epidemiology, explain to the jury what that means. What is an endpoint? A. An endpoint is the way that the physician calculates how many patients they need in a clinical trial. That's a primary endpoint. It's slightly confusing, but there is different definitions or different categories of endpoints in a study. It's basically the point to the study. You could think of it that way. The primary endpoint is the way the physicians figure out how many patients they need. So, they might ask a question of what's the rate of objective success, how many patients are improved in my study. They have to determine how many patients they need to answer that question. The primary endpoint drives that calculation. It's a 485 statistical method to get that calculation. There are also secondary endpoints. Secondary endpoints you can also do the same thing. If you have a question in the secondary endpoint and you want to get a statistical significance around that, you can then figure out how many patients you need to do that. It doesn't mean that the primary is more important or it's the only importance in the study and the secondary endpoints don't have value. They're basically all endpoints. They're all the questions that you have about this intervention. But the primary endpoint is how you figure out how many patients you need to prove that one endpoint. Q. So, the primary endpoint verses secondary endpoint is kind of a statistical calculation? A. Yes.		

21 Q. In terms of importance, does -- if 22 something is a secondary endpoint, does that mean 23 it's of secondary importance?		
jc042115, (Pages 486:4 to 487:14) 486 4 A. No. No. All of the endpoints are 5 important. They're all reported on the clinical 6 studies. So, there are secondary endpoints about 7 economic. There are secondary endpoints about 8 safety. It doesn't mean those questions are not 9 as important as the first question about 10 objective success, for example. 11 It just means that the way you 12 calculate how many patients you need -- you can 13 only do it one way. You can't use many different 14 statistical ways to do it. So, you have to 15 basically chose one of those questions to power, 16 to figure out how many patients you need in a 17 study. They're not of lesser importance. 18 Q. When Boston Scientific is looking at 19 the studies and the data, are there different 20 ways in which doctors are evaluating how 21 satisfied the patients were or how satisfied the 22 doctor is with the treatment? 23 A. There can be. There are 24 questionnaires the patients are given to answer. 25 That they are given these questionnaires before 487 1 their treatment and they're given them after 2 treatment at all those different times they come 3 back to see their physician. 4 So, for example, there is 5 questionnaires asking questions about how 6 distressed they are with their pelvic floor 7 symptoms. So, the patient specifically answers 8 how do these symptoms affect their daily life, 9 physical activity, social activities, sexual 10 activities, energy level, emotional level. And	486:4-487:14 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

11 they answer those same questions at each time. **12 So, the physicians, the companies,** **13 other physicians will understand how the patients** **14 are reacting to their therapy.**		
jc042115, (Page 494:9 to 494:16) **494** **9 (Exhibit 1330, Timeline: POP** **10 devices, marked)** **11 Q. (By Mr. Anielak) Quickly tell the** **12 jury what this represents.** **13 A. So, it's an outline of the timeline** **14 of when the Boston Scientific pelvic organ** **15 prolapse devices were marketed and then the** **16 competitor devices.**	**494:9-16 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**
jc042115, (Pages 495:2 to 500:2) **495** **2 Q. (By Mr. Anielak) So, with regard to** **3 the POP devices, Uphold and Pinnacle were** **4 launched in 2008 and 2009 time period, right?** **5 A. That's correct.** **6 Q. And, so, deciding whether or not a** **7 clinical trial was necessary prior to going to** **8 market, how did the -- how did Boston Scientific** **9 rely on the other devices that were already on** **10 the market?** **11 A. So, we basically -- if you look at** **12 when the Pinnacle and Uphold were launched, there** **13 is or are many products that were already on the** **14 market.** **15 So, specifically from Boston** **16 Scientific's standpoint, the Polyform mesh was on** **17 the market. And there were data available on the** **18 use of Polyform mesh for pelvic organ prolapse.** **19 So, Boston Scientific looked at** **20 these devices, reviewed the clinical data that** **21 was available on all these devices prior to** **22 launching the Pinnacle and Uphold. So, all that**	**495:2-500:2 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

information was available to us.
Q. So, was there information and data available regarding the use of these devices in

496

women prior to Uphold and Pinnacle being sold?
A. Yes.
Q. And, was there data that Boston Scientific could review on Polyforms performance in women prior to going to market with Pinnacle and Uphold?
A. There was. So, Boston Scientific has a program internally where we monitor all of our devices. So, it's a safety surveillance program. So, we had information on the use of Polyform in Boston Scientific to understand then the use of that device in the Pinnacle and Uphold.
Q. So, explain that in a little bit more detail to the jury.
What is the data that Boston Scientific had to consider with regard to the performance of Polyform in terms of its performance in women?
A. So, safety data. So, we had data internally on any events that patients experienced or any device issues that physicians experienced. And that information is recorded internally to Boston Scientific, which we had the ability to review prior to the launch of Pinnacle

497

and Uphold.
Q. Is it common in the medical device development for companies to rely upon similar devices in terms of making decisions as to whether a clinical trial is necessary prior to going to market?
A. Yes, it is.
Q. So, explain that to the jury. Why is that something that medical device companies

do? A. When you're marketing a device, whether it's, you know, brand new, never been used before, or if it's similar to others, which is an example for these devices. You will look at existing literature to understand, is there information already known that will assist in the understanding of should a trial be done, what information will it add, is there value in terms of missing conclusions, is there anything more to be learned. So, that is typically -- and how companies and clinical research will proceed forward. Q. And, with regard to the Pinnacle and Uphold device. Explain for the jury what Polyform 498 is and what Capio is and how that relates to Pinnacle and Uphold? A. Polyform is a polypropylene mesh, and it's a sheet mesh. So, it's not cut to a certain small shape. It is a, basically a square, rectangle, rectangle sheet of mesh. And the physicians, when they have -- when they use this product, they will cut the mesh to a certain shape, and then use the capio, which is a suturing device and place sutures through that Polyform mesh, the other end of the Capio and place it into the anatomy to then fixate that into the body. That's what poly -- well, that's how Polyform was used in many different instances in 2005 forward. Pinnacle device is basically taking the polyform and the Capio, putting it in a package together, but already doing the shaping and the fixating to a delivery system in that package, basically, if that makes sense. So, the Capio system is still part of that because the Capio is used to place it in the body, but the Pinnacle was basically taking the Polyform, putting it into a shape, and allowing for kind of a standardization for that		

499 1 procedure. 2 Q. And, was the Uphold similar in terms 3 of using Polyform and cutting it into a shape? 4 A. Correct. So, it's just a different 5 and different fixating points that go in the 6 body. So, it is the similar situation where it's 7 Polyform into a shape with the Capio device. 8 Q. Okay. So, in terms of the mesh 9 that's used in Pinnacle and Uphold. 10 Was the mesh new, a new product on 11 the market in 2008? 12 A. No. 13 Q. And, was the use of polypropylene to 14 treat pelvic organ prolapse, was that something 15 that Boston Scientific came up with in 2008? 16 A. No. 17 Q. And, explain that to the jury. 18 A. No. So, if you look at the 19 timeline, these are polypropylene devices in 20 orange or in the other colors that are prior to 21 Pinnacle and Uphold, even Polyform. 22 Q. And, did Boston Scientific rely upon 23 the prior marketing of those devices in making a 24 determination that a clinical trial prior to 25 going to market wasn't necessary? 500 1 A. Right. So, we did review all that 2 information to make that decision.		
jc042115, (Page 501:6 to 501:10) 501 6 Q. (By Mr. Anielak) Ms. Connor, did 7 you help put together some slides that summarize 8 the clinical studies that had been conducted with 9 Boston Scientific devices? 10 A. I did.	501:6-10 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jc042115, (Pages 508:20 to 510:1) 508 20 Q. And, then, you were asked some 21 questions about degredation. 22 Do the clinical trials that had been	508:20-510:1 FRE 401, 402 403, 701 702	

23 conducted, the more than 30 clinical trials show **24 evidence of widespread degredation in Boston** **25 Scientific slings?** **509** **1 A. No, they do not.** **2 Q. And, explain that to the jury.** **3 A. If degredation were to occur, you** **4 would definitely see it in these studies, and** **5 you'd see it different. You'd see it in** **6 different ways. So, the way that degredation --** **7 degredation is basically the mesh falling apart.** **8 It could fall apart overtime. It** **9 could be -- manifest itself in certain** **10 complications. And also ineffectiveness. So, if** **11 we think about the mesh's intent is to support** **12 the anatomy in one way or another, if that mesh** **13 were degrading that support would fail.** **14 So, you would see overall widespread** **15 rates. So, again, how many patients experience** **16 this event over how many total. You would see** **17 that as being a very high rate of failure.** **18 So, patients at different time** **19 points would be failing and that rate would be** **20 increasing over time. And, that's how you** **21 basically see evidence, which we don't see.** **22 Q. Do you see widespread evidence of** **23 product failure in the clinical studies that have** **24 been done with Boston Scientific slings?** **25 A. No. In the slings, the evidence of** **510** **1 success is over 90%. So, no.**		
jc042115, (Pages 544:9 to 545:21) **544** **9 Q. And, what is AUGS?** **10 A. AUGS is the -- it stands for the** **11 American Urogynecologic Society. Is a national** **12 nonprofit group of physicians in the United** **13 States with a mission of studying and supporting** **14 pelvic floor disorders.** **15 Q. And, did Boston Scientific write**	**544:9-545:21 FRE 403, 802**	***[Counter Designations to 544:9-545:21]*** ***jc042115, (Page 655:1 to 655:12)*** ***655*** ***1 Now, I want you to first look at --*** ***2 and I don't know what number it was marked as,***

this AUGS position statement? **A. No.** **Q. And, what did AUGS, the American Urogynecologic Society, those physicians, what did their organization conclude with regard to the polypropylene mesh midurethral sling?** **A. Well, there's many different areas within this statement that they have kind of general conclusion statements.** **But, overall they stated that the** **545** **polypropylene mesh midurethral sling is the recognized worldwide standard of care for the surgical treatment of stress urinary incontinence. The procedure is safe, effective, and has improved the quality of life for millions of women.** **Q. And, do the AUGS, as part of this statement, do they reference the literature and the study that has been done of polypropylene devices used to treat stress urinary incontinence?** **A. Yes, they do.** **Q. And, in terms of their evaluation of the clinical literature, what have they -- what did AUGS conclude with regard to the polypropylene sling?** **A. So, again, some of the sections in here. So, one of them states that the Monofilament Polypropylene Mesh Midurethral Sling is the Most Extensively Studied Anti-Incontinence Procedure in History.**		*but the AUGS position statement, correct?* *A. Okay.* *Q. And, I want to make sure that I'm understanding this. What your position, as Boston Scientific is, is that the AUG statement saying that midurethral slings generally are safe means that your Boston Scientific midurethral slings are safe, correct?* *A. Correct.* *jc042115, (Page 656:3 to 656:9)* *656* *And, it's best to get that information from someone who, for lack of a better term, doesn't have a dog in the fight, right?* *A. Who doesn't have a conflict of interest in the results, if that's what you mean.* *jc042115, (Pages 656:10 to 660:11)* *656* *Q. So, one of the reasons that you cited to the AUGS statement is that you told the jury that it was quote/unquote an independent finding, correct?* *A. Correct.* *Q. And, that you believed that it was a neutral finding and analysis, correct?* *A. A neutral review. Do you mean -- I'm confused by the word finding.*

		19 Q. It was conducted in a neutral *20 manner, correct?* *21 A. Correct.* *22 Q. Now, there are one, two, three,* *23 four, five people who are identified as the* *24 authors on this editorial, correct?* *25 A. Correct.* *657* *1 Q. Are you aware that Charles Nager,* *2 the first author listed, is a highly-paid* *3 consultant for Ethicon, a competitor of Boston* *4 Scientific that makes the TVT and TVT-O devices* *5 as we discussed?* *6 A. Is he still a highly-paid consultant* *7 today?* *8 Q. Do you know?* *9 A. Well, he is the current president of* *10 AUGS. So I know that part of that presidency* *11 means he can't have conflicts of interest with* *12 industry.* *13 Q. You know that Dr. Nager has been* *14 paid a lot of money by Ethicon as a consultant on* *15 their polypropylene mesh products in the past,* *16 don't you?* *17 A. In the past.* *18 Q. Okay. And you know that Dr.* *19 Tulikangas has been paid a lot of money by* *20 Eithicon for their polypropylene mesh products,* *21 correct?* *22 A. Correct.* *23 Q. And, you know that Dr. Rovner has*

		been paid by Ethicon as a consultant, correct, on its polypropylene mesh products, right? *658* *A. I don't know Dr. Rovner.* *Q. So, you don't know that?* *A. I don't know that.* *Q. Do you think that's material to your decision as to whether this is an independent or neutral statement?* *A. It's not because there is actually a 2015 paper where he talks about the potential bias of that where he clearly states that industry had nothing to do with that, but.* *Q. Okay.* *A. Continue.* *Q. Dr. Goldman. He is also a paid consultant for Ethicon, correct?* *A. I don't know Dr. Goldman. I'm not aware of that.* *Q. But you know Dr. Miller, don't you?* *A. I do.* *Q. Okay. Who is Dr. Miller?* *A. Dr. Miller is a consultant for Boston Scientific and was the inventor of the Pinnacle product.* *Q. And, Dr. Miller has actually been* *659* *paid millions of dollars in royalties from Boston Scientific in connection with his Pinnacle product, correct?*

		4 A. I believe so, yes. *5 Q. And, he is someone with whom Boston* *6 Scientific has a very close relationship with,* *7 correct?* *8 A. That's correct.* *9 Q. And, he is someone with whom Boston* *10 scientific consulted with over the years on* *11 polypropylene mesh issues?* *12 A. Correct.* *13 Q. Okay. So, at least, to your* *14 knowledge, three of the five people who wrote* *15 this paper work with industry to develop* *16 polypropylene mesh products, correct?* *17 A. That is true. But back to my* *18 statement, there is a follow-up paper here on Dr.* *19 Nager's presidential address at AUGS last year* *20 where he clearly states emphatically that* *21 industry had nothing involved in this position* *22 statement.* *23 Q. Ms. Connor, did you expect him to* *24 get up and say, listen, it's all a sham. We were* *25 all paid by Ethicon?* *660* *1 MR. ANIELAK: Form.* *2 THE WITNESS: I trust Dr. Nager.* *3 He's an honest physician respected by the* *4 entire community of AUG, so.* *5 Q. (By Ms. Fitzpatrick) But it is also* *6 a self-serving statement by Dr. Nager to say I*

		7 did this independently and not the behest of the *8 company that's paid me lots of money, right?* *9 MR. ANIELAK: Form.* *10 THE WITNESS: I don't know the* *11 answer to that.*
jc042115, (Pages 548:22 to 549:21) **548** **22 Q. (By Mr. Anielak) Then the final** **23 conclusion by AUG states, this procedure is** **24 probably the most important advancement in the** **25 treatment of SUI in the last 50 years and has the** **549** **1 full support of our organizations, which are** **2 dedicated to the lives of women with urinary** **3 incontinence.** **4 A. I see that, yes.** **5 Q. And, on your review of the clinical** **6 literature.** **7 Do you see that there is clinical** **8 studies supporting the use of polypropylene mesh** **9 to treat stress urinary incontinence?** **10 A. I do. So, through supporting it** **11 means that the research continues. There are** **12 still studies on these devices and those results** **13 of the studies aren't different from what we've** **14 already known. So, similar to another article.** **15 The data continue to be similar and supporting** **16 the use of the devices.** **17 (Exhibit 1338, IUGA, marked)** **18 Q. (By Mr. Anielak) I've marked as** **19 deposition Exhibit No. 1338 a statement from** **20 IUGA.** **21 Do you see that?**	**548:22-549:21** **FRE 403, 802**	*[Counter Designation to 548:22-549:21]* *jc042115, (Pages 661:14 to 664:23)* *661* *14 (Exhibit 12352, emails, marked)* *15 Q. (By Ms. Fitzpatrick) Okay. Ms.* *16 Connor, you actually know who Dr. Tulikangas is,* *17 don't you?* *18 A. I know him. I don't know him* *19 well.* *20 Q. Okay. And, you know that Boston* *21 Scientific for a significant period of time was* *22 trying to convince Dr. Tulikangas to use its* *23 Obtryx, Advantage, and Lynx devices, correct?* *24 A. Correct.* *25 Q. And Boston Scientific had approached* *662* *1 Dr. Tulikangas and said to him, consider* *2 switching over and consider switching to our* *3 devices, correct?* *4 A. Correct.* *5 Q. And, Dr. Tulikangas wouldn't do* *6 that, correct?* *7 A. At this time, yes.* *8 Q. So, let's take a look at what I have* *9 identified as plaintiff's Exhibit 1352.* *10 Okay?*

		A. Okay. *Q. And, that is a series of emails going back to September 6, 2011.* *Do you see that?* *A. I do.* *Q. And, they are emails that are coming, first, from Dr. Tulikangas to Anthony Parrillo, Adam Steinberg, and Christine LaSala.* *Correct?* *A. Yes.* *Q. And, those are all BSC employees, right?* *A. No. Adam Steinberg is a physician. Tim Cody a BSC. Anthony Parrillo is BSC. And the other two I'm not familiar with.* *663* *Q. Okay. So, in this Dr. Tulikangas -- and let me put this up on the screen.* *So, you have a Boston Scientific representative who is attempting to convince Dr. Tulikangas to use Boston Scientific's slings in his patient, correct?* *A. Correct.* *Q. And, Dr. Tulikangas has asked Boston Scientific for some literature to support the safety and efficacy of the Advantage and the Obtryx, correct?* *A. I believe so based on the fact that Anthony had sent him an email with all the different clinical data.* *Q. Okay. And, Dr. Tulikangas, who was*

		16 one of the authors of the Gold Standard Generic *17 Midurethral Sling Polypropylene, wasn't willing* *18 at this point to just rely on data concerning the* *19 TVT and other midurethral slings, correct?* *20 A. At this time, yes.* *21 Q. And, he asked Boston Scientific to* *22 prove to him that your sling performed as well as* *23 the competitors products, correct?* *24 A. Correct.* *25 Q. And, he was not willing to make the* *664* *1 leap of faith that Boston Scientific had made* *2 back in 2002 that Advantage and TVT, close* *3 enough, they must perform the same way?* *4 MR. ANIELAK: Form.* *5 THE WITNESS: So, he had comments,* *6 the limited data here, that showed the* *7 product to be inferior.* *8 Q. (By Ms. Fitzpatrick) Okay. So,* *9 Mr. Parrillo, who is from Boston Scientific, sent* *10 Dr. Tulikangas a summary of some of the very same* *11 literature that's sitting in front of you that* *12 you've discussed to date, correct?* *13 A. Correct.* *14 Q. And, he was attempting to convince* *15 Dr. Tulikangas to use your Boston Scientific* *16 products based on the very same literature you're*

		17 sitting here talking to the jury about today, *18 correct?* *19 A. Correct.* *20 Q. And, Dr. Tulikangas looked at that* *21 literature and he said, no, I think your products* *22 are inferior, correct?* *23 A. That's correct.*
jc042115, (Pages 549:23 to 551:2) **549** **23 THE WITNESS: I do.** **24 Q. (By Mr. Anielak) And, what is** **25 IUGA?** **550** **1 A. It's an international organization** **2 similar to AUGS, where AUGS is in the United** **3 States, IUGA stands for the International** **4 Urogynecological Association. So, it's an** **5 international nonprofit group with a mission to** **6 study pelvic floor disorders.** **7 Q. And, did Boston Scientific have** **8 anything to do with the drafting of this position** **9 statement from IUGA?** **10 A. No.** **11 Q. If you turn over to the second page.** **12 Did IUGA comment on the clinical** **13 literature and the clinical studies of slings?** **14 A. Yes. So, they indicate here that** **15 there is robust evidence to support the use of** **16 midurethral slings from over 2,000 publications** **17 making this treatment the most extensively** **18 reviewed and evaluated procedure for female** **19 stress urinary incontinence now in use.** **20 Q. And, based on those studies, what** **21 did IUGA conclude with regard to the use of** **22 polypropylene slings to treat stress urinary** **23 incontinence?** **24 A. So, as a result, IUGA supports the** **25 use of monofilament polypropylene midurethral** **551** **1 slings for the surgical treatment of female** **2 stress urinary incontinence.**	**549:23-551:2 FRE 403, 802**	

jc042115, (Pages 551:9 to 552:14) **551** **(Exhibit 1339 marked for identification)** **Q. (By Mr. Anielak) And, I've marked as deposition Exhibit 339.** **Describe for the jury what this is.** **A. It's a summary of the studies that have been performed on Pinnacle and Polyform.** **Q. So, why Pinnacle and Polyform together?** **A. So, Polyform is basically -- the Polyform mesh is a sheet mesh. Pinnacle is using that Polyform mesh in a certain shape. So, it's basically the Pinnacle device is the Polyform mesh with the Capio device.** **Q. And, how many women have been treated in those studies?** **A. Over 700.** **552** **Q. And, the slide says that the study has been presented at medical conferences or published.** **Describe for the jury what that means.** **A. So, that means when the studies are complete that all of these studies have either been presented at those medical society conferences. So, again, that means the physician is standing there presenting the data or has published the data in a poster format and can speak to it that way. Or the data were presented -- published in a medical journal in the form of a manuscript.**	**551:9-552:14 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**
jc042115, (Pages 552:15 to 555:3) **552** **Exhibit 1340 marked for identification)** **Q. (By Mr. Anielak) I want to transition to just the Pinnacle studies.** **How many studies have been performed just on the Pinnacle device?** **A. That's 11.** **Q. And, what have the length of those studies been?** **A. So, it ranges. So, again, the**		

length of time is when a patient is seen after 553 treatment. So, ranges from one month out to three and a half years. Q. And, the studies have been performed with 40 different investigators. Right? A. That is correct. Q. And, describe for the jury what an investigator does and what his role or her role is in the clinical study? A. An investigator basically is the physician who is responsible for the research. So, it could be multiple physicians at a center, at a hospital. But the physicians are treating the patients, asking the questions, following the patients. Q. And, in terms of the studies that have been done on Pinnacle, are some of those studies funded and supported by Boston Scientific? A. Yes. Q. And, are some of the studies then conducted by independent physicians? A. Yes. Q. And, when evaluating the literature for Pinnacle or for any of Boston Scientific devices, does Boston Scientific look at one study 554 and one finding or does Boston Scientific look at the overall body of work? A. No. So, we do look at individual studies, but we don't make conclusions off an individual study. So, we look at the whole body of literature, but we don't look at one study and then determine that that study is the only study to be looked at. It's part of the broad spectrum of data. Q. So, in terms of success rate. Generally, is the Pinnacle -- has it been shown to be successful in treating pelvic organ prolapse? A. It has. So, in the studies that we refer to here, the data show it has over a 90%	554:11-21 Foundation, FRE 401, 402, 402, 701, 702, 802, 1006	

17 success rate. So, that means over 90% of the 18 women treated with the device have improvements 19 in their symptoms from pelvic organ prolapse or 20 they've -- the anatomy is basically in an 21 improved location. 22 (Exhibit 1341 marked for 23 identification) 24 Q. (By Mr. Anielak) Continuing to talk 25 about success rates. 555 1 Did you help put together this slide 2 that summarizes some of the success rates from 3 the clinical trials?		
jc042115, (Pages 555:5 to 559:18) 555 5 THE WITNESS: Yes. So, this is a 6 chart that lists all of the Pinnacle 7 studies that have been performed. And, 8 basically, is a summary from all of those 9 studies on what the authors concluded for 10 effectiveness. 11 Q. (By Mr. Anielak) So, in terms of 12 effectiveness for Pinnacle, how is that 13 evaluated? How are doctors looking to see 14 whether or not Pinnacle was effective in treating 15 pelvic organ prolapse? 16 A. So, they're looking to see where 17 that bulge of prolapse is. So, patients will 18 report a bulge, a symptom, a feeling. 19 So, they're looking to see, they're 20 asking the patients, do they still feel that. 21 Or -- and also doing a pelvic exam. So, to see 22 where that organ is, is it still in the same 23 location it was prior to surgery and; therefore, 24 it's not successful. Or is it back to its normal 25 or more appropriate position. 556 1 Q. Okay. 2 A. Location. 3 Q. And, the studies, as you summarize 4 on the slide, talk about excellent anatomic 5 outcome or apical support. There is another 6 reference to anatomic results. 7 Describe for the jury when the 8 investigators are looking at excellent, apical	555:5-559:18 FRE 401, 402 403, 701, 702, 802, 1006	

support or excellent anatomic outcomes. What are they referring to? A. So, they're referring to the actual anatomy. Apical support means that there is a location in the vagina, basically, where the anatomy should be. So, the top of the vagina. So, that should be in a certain location. If that -- if the uterus or that area is prolapsed, it changes to a different location and out of its normal location. So, when they mean there is excellent apical support, that means that that apex, that top of the vagina, is being supported by the mesh, sutures, and it's in the right location, basically. Q. And, then there are also references to subjective success. 557 When the investigators report that there is good subjective success, what are they referring to? A. So, subjective success refers to the patients report of success. So, in a pelvic organ prolapse study, the patients are responding as to, do they feel a bulge. Again, if there is an organ prolapsing, it's falling and you can feel that. So, from what the patients report. So, they're answering the question that they don't feel that anymore. Or, if they feel it, it doesn't bother them. It's nowhere near how it felt or how much it bothered them prior to that surgery. So, that means that from their point of view they are successful. Q. Okay. And, in terms of the overall conclusion from the Pinnacle studies in terms of effectiveness, what, in general, do the studies show regarding Pinnacle's effectiveness? A. You know, overall. So, as we talked about, these are all the studies. So, all of these studies have positive conclusions about the effectiveness from the authors point of view. So, these are the authors words		

558 1 indicating that the success rates were over 90% 2 for mostly all of these. I believe all of them. 3 The patients were reporting that 4 they were successful. And, also, some of these 5 papers also report that no patient had to have 6 another surgery to treat their prolapse, that 7 that did not occur. 8 Q. Okay. 9 (Exhibit 1342 marked for 10 identification) 11 Q. (By Mr. Anielak) Do the studies 12 also look at complications like erosion? 13 A. Yes. 14 Q. And, in terms of erosion rates that 15 have been seen in the Pinnacle studies. 16 What has been shown in the clinical 17 studies with regard to erosion rates? 18 A. This is a chart that, again, 19 illustrates those Pinnacle studies that we had 20 talked about, the number of patients in the 21 study, and then what that rate of erosion was 22 reported in that group of patients in that 23 specific study. 24 Q. And, when we talk about erosion in 25 the course of clinical studies, describe for the 559 1 jury what that means today verses what that may 2 have meant in these particular studies? 3 A. Yeah. So, erosion is also used a 4 lot of times in these older studies as exposure. 5 So, the terms erosion/exposure were 6 used interchangeably, again, in a lot of these 7 early studies. 8 So, for this study, erosion 9 basically is meaning that the physicians are 10 reporting that the mesh itself, some threads of 11 the mesh or pieces of the mesh were being exposed 12 to the tissue. Or there -- or it was basically 13 parts of the tissue were eroding. So, further 14 into the body. 15 Q. And, then, in terms of the treatment 16 for erosion, are there different kinds of 17 treatment or different types of erosion or 18 exposure that occur?		
jc042115, (Pages 559:21 to 561:6) 559	550:21-561:6	

THE WITNESS: So, looking at this table, first off the rates range from zero percent up to 27.9 and there are reasons for that. **If mesh is placed in the body there** **560** **are many different reasons why exposure might occur, one of them is due to healing. So, the mesh is placed and tissue is then placed over it and sutured with stitches. If that was not done appropriately, the mesh itself can actually come through the tissue.** **Also it could be -- exposure could occur due to tissue quality, the tissue itself is of poor quality. And, so the healing process is impaired. And there is lots of other reasons in terms of patient factors, experience with radiation, other -- diabetes. Other comorbidities we call them. Other diseases that the patient might have. So, all of these contribute to erosion.** **So; therefore, the treatment of it depends. So, many times -- and I think the majority of some of the recent studies, if exposure occurs, it's treated in a minor way. So, the patients come to the physician's office. There is usually cream placed in that area and the exposure resolves or its trimmed. Whatever is** **561** **exposed, that there will be pieces of that mesh trimmed and the patients sent home. So that is one area.** **Patients can come back to the OR, but that's not as common as the minor treatment.**	**FRE 401, 402, 403, 701, 702**	
jc042115, (Pages 562:3 to 564:22) **562** **Q. (By Mr. Anielak) I don't want to talk about all of the Pinnacle studies, but what is Exhibit 1343?** **A. This is an excerpt from the Female Pelvic Medicine & Reconstructive Surgery Journal in 2012. And, it includes as abstract of a Pinnacle study by Dr. Peter Rosenblatt.** **Q. And this particular study is titled -- is described as being long-term?**	**562:3-564:22** **FRE 403, 802**	***[Counter Designation to 562:3-564:22 Deposition of Matthew Davies, MD taken 12/29/2014]*** ***md122914, (Page 9:13 to 9:15)*** ***9*** ***Q. Please state your name for the record.*** ***A. Matthew Davies.***

A. Yes. **Q. And, why did Dr. Rosenblatt describe this study as being long-term?** **A. So, he reports data on an average follow-up time period of 27.2 months.** **Q. And, during what period of time was Dr. Rosenblatt treating his patients for this particular study?** **A. They were collecting data on patients treated from July, 2008, to October, 2010.** **Q. And, how long was the follow-up with those particular patients?** **A. It ranged. So, the average was 27.2 months, but it ranged from a year to almost four years.** **Q. And there were 213 patients in this particular study?** **A. That's correct.** **Q. And, did Boston Scientific support this study through it's ISR program?** **A. Yes.** **Q. And, in terms of effectiveness, what did -- what did the study show in terms of the effectiveness of the Pinnacle device?** **A. In terms of effectiveness, I believe -- if you'll give me one minute. I believe that they reported information if patients had a reoperation, which I believe -- ah-ha. It says, "No patients underwent reoperation for prolapse" in the conclusion.** **Q. And, then in terms of evaluating the safety and complications of Pinnacle.** **What data was looked at with regard to safety and complications?** **A. So, there is a few complications they report. So, they talk about mesh exposure.** **And the incidence of mesh exposure was 4.2%.** **They also list UTI, urinary tract infection, at 2.8. Infection or other, 1.9. Voiding difficulty, other complications.** **They indicate that no procedure related adverse events required surgical intervention.**		*md122914, (Pages 102:23 to 103:9)* *Q. The next sentence, you write, "Specific to the Pinnacle, I'm a leading author on a multi-center study that evaluated 213 patients implanted with the Pinnacle for a mean of 27.2 months, range of 12 to 43 months."* *Did I read that correctly?* *A. Yes, you did.* *Q. Is this the Rosenblatt abstract that you were a coauthor with?* *A. Yes.* *md122914, (Page 144:13 to 144:20)* *Q. We'll mark Exhibit 14 to your deposition.* *And this is a online abstract submission, correct?* *A. Correct.* *Q. And this is dated April 5, 2012?* *A. Yes, it is.* *md122914, (Pages 151:10 to 154:11)* *Q. Doctor, who wrote the retrospective Pinnacle study?* *A. I believe Peter Rosenblatt*

And, overall, they state that the global incidence of surgical reoperation following repair with a Pinnacle kit was 5.2%. **Q. So, in terms of the mesh exposure, mesh exposure in this particular study was seen in 4.2% of women?** **A. Correct.** **Q. And, what did the investigators, Dr. Rosenblatt and his other physicians conclude with regard to the Pinnacle study in the performance of this particular study?** **A. So, they state here in the abstract that in this retrospective study, long-term results support the safety and effectiveness of the Pinnacle PFR kit with low mesh exposure and no documentation of patient complaints of recurrent prolapse.**		*wrote the bulk of it and then sent it for review several times to all of us.* *Q. Have you ever heard of a company called Compass Point Research?* *A. Yes. That -- I was trying to think of the name earlier. And you said we'll come back to that. That was the name, Compass Point Research.* *Q. What is your understanding of what they do?* *A. It's very little understanding except I think that they* *152* *basically are a research firm that helps to send out people to multi-centered sites for data acquisition, whether it be prospective or retrospective in studies.* *Q. Do they write studies?* *A. I would imagine that they have writers and statistical analysis people who help authors, for example, with statistical analysis which is a huge burden a lot of times. So they may have their own -- their own biostatisticians.* *md122914, (Page 192:17 to 192:22)* *192* *Q. When did you become aware of*

		18 the other authors listed on the abstract *19 involvement in the Pinnacle retrospective* *20 study?* *21 A. Probably with the first* *22 submission of the draft, if I can say.* *md122914, (Pages 193:20 to 194:18)* *193* *20 Q. We'll mark Exhibit 17 to* *21 your deposition.* *22 And as you're aware, we go* *23 from the back to the front when we read* *24 these e-mails.* *194* *1 A. Oh, okay.* *2 Q. I'll direct your attention* *3 to Bate label 889.* *4 A. Okay. I'm there.* *5 Q. This is an e-mail from David* *6 Russell to Janice Connor entitled,* *7 "Pinnacle Update," dated August 17, 2011,* *8 correct?* *9 A. Correct.* *10 Q. And here, David is telling* *11 Janice, "Per our conversation on Monday,* *12 here's where we are, retrospectives in* *13 the database, 109," correct?* *14 A. Correct.* *15 Q. Is that referring to cases* *16 for the retrospective review?* *17 A. That's what I would* *18 interpret that to mean.*

		md122914, (Page 195:2 to 195:17) *195* *2 Q. And we see, "Rosenblatt, 75* *3 potential cases," correct?* *4 A. Correct.* *5 Q. And Ralph Chesson in* *6 New Orleans, Louisiana, has a hundred* *7 potential cases, correct?* *8 A. Correct.* *9 Q. And then you have a hundred* *10 potential cases as well?* *11 A. That's correct.* *12 Q. And the total is -- flip the* *13 page --* *14 A. 384?* *15 Q. -- says, "384 cases,"* *16 correct?* *17 A. Correct.* *md122914, (Page 198:10 to 198:12)* *198* *10 Q. And so, Doctor, can you and* *11 I agree that 384 is less than 213?* *12 A. I can agree on that.* *md122914, (Pages 199:5 to 200:1)* *199* *5 Q. Doctor, you testified* *6 earlier that you were blinded as to the* *7 data coming from the other centers in the* *8 retrospective Pinnacle study?* *9 A. That's correct.* *10 Q. Do you know how many total*

		11 Pinnacle cases were in the Compass Point *12 database when enrollment closed?* *13 A. I don't. I only know how* *14 many were published.* *15 Q. And so you don't know* *16 whether there were 384 potential* *17 retrospective cases for the Compass Point* *18 review, do you?* *19 A. Or 500.* *20 Q. All you know is that the* *21 Compass Point people came to your site,* *22 extracted information, and that at some* *23 point later on you received a manuscript* *24 in the mail, correct?* *200* *1 A. That's correct* *md122914, (Page 202:8 to 202:21)* *202* *8 Q. Did you trust Compass* *9 Point's statistical analysis of your data* *10 and the data coming from other centers?* *11 A. Oh, yes.* *12 Q. You did not independently* *13 verify their statistical analysis of the* *14 final product?* *15 MR. SODEN: Objection to* *16 form.* *17 THE WITNESS: No, I didn't* *18 go gather the 213 patient data* *19 points and then have a separate*

		20 statistical analysis from it. *md122914, (Pages 203:20 to 204:20)* *203* *20 Q. If we looked at Janice's* *21 reply dated August 22nd, 2011, Janice* *22 writes, "Hi, David. Thank you for the* *23 update. As we discussed, I would like to* *24 wrap up both studies enrollment-wise by* *204* *1 end of September."* *2 Did I read that correctly?* *3 A. You did.* *4 Q. Doctor, why is Janice Connor* *5 providing input as to when the enrollment* *6 should close on a study that you're the* *7 author of?* *8 MR. SODEN: Object to the* *9 form of the question.* *10 Speculation.* *11 THE WITNESS: Well, she's* *12 not writing to me. She's writing* *13 to Compass Point, I assume is* *14 where David Russell is. And she's* *15 just writing to say that I'm* *16 hoping that we'll have enough* *17 patients enrolled that we can stop* *18 enrollment by September. So can* *19 you give me an update, is all* *20 she's asking.*

		md122914, (Page 205:9 to 205:17) *205* *9 Q. Janice goes on to write,* *10 "Also, please start thinking of the* *11 manuscript writing and conference* *12 submission for the retrospective study.* *13 You will need a physician who can lead* *14 this for you, obviously, typically, the* *15 lead enroller."* *16 Did I read that correctly?* *17 A. Yes, that's perfect.* *md122914, (Pages 208:18 to 210:4)* *208* *18 Q. Dave goes on to write, "I* *19 will get with Lori ASAP on the manuscript* *20 and writing. We do already have a writer* *21 and stats person lined up for the* *22 project. I will get you a list of* *23 potential conference targets."* *24 Did I read that correctly?* *209* *1 A. Yes.* *2 Q. Who was the writer of the* *3 retrospective Pinnacle study, Doctor?* *4 MR. SODEN: Object to the* *5 form of the question.* *6 THE WITNESS: Well, it*

		sounds to me like they probably have somebody in their organization who can write down the methods part of it, because it's spelled out there already in the IRB proposal, and they can get the stats started without the actual numbers in there. The numbers are in a database to bring over. They can do all that. But then they're going to have to get a lead physician, like Peter Rosenblatt, to really put in the clinical components to it, introduction, interpretation, discussion. *BY MR. CASPERSON:* *210* *Q. Is a writer different than an author?* *A. Yeah. I would definitely say so.* *md122914, (Pages 210:12 to 211:8)* *210* *Q. Doctor, do you know who the stats person David Russell is referring to in this e-mail?* *A. I don't actually.*

		16 Q. Do you have any idea whether *17 they're an honest person with integrity?* *18 MR. SODEN: Object to the* *19 form of the question.* *20 THE WITNESS: You're asking* *21 me to predict something about* *22 somebody I don't even know.* *23 BY MR. CASPERSON:* *24 Q. You don't know who they are,* *211* *1 correct?* *2 A. Right. So how could I* *3 predict their integrity and honesty?* *4 Q. So would you agree with me* *5 that you don't know who the individual* *6 was who did the statistical analysis on* *7 the data extracted from your site?* *8 A. That's correct.* *md122914, (Page 219:7 to 219:23)* *219* *7 Q. David goes on to write, "We* *8 also have the word out to the site* *9 New Orleans that the database should be* *10 ready. That site has chosen to enter* *11 their own data."* *12 Does that contain any* *13 significance to you, Doctor?* *14 A. No, that might just be their*

		15 institutional rule, and then they'll send *16 the data in that form to Compass Point.* *17 Q. Well --* *18 A. So the cost may have been* *19 the issue there.* *20 Q. Can we agree that the* *21 New Orleans site is referring to Ralph* *22 Chesson?* *23 A. Uh, yeah, I assume* *md122914, (Pages 221:16 to 222:5)* *221* *16 Q. So would you agree that* *17 according to this e-mail, the New Orleans* *18 site, Dr. Ralph Chesson, chose to enter* *19 his own data for the Pinnacle* *20 retrospective study?* *21 MR. SODEN: Same objection.* *22 THE WITNESS: That's what it* *23 says, so I'll save it, that's* *24 probably accurate.* *222* *1 BY MR. CASPERSON:* *2 Q. And Ralph Chesson is not an* *3 author on the abstract you submitted to* *4 AUGS and IUGA?* *5 A. That's correct.* *md122914, (Page 226:12 to 226:22)* *226* *12 Q. We'll mark Exhibit 18 to* *13 your deposition.*

		14 This is a -- an e-mail from *15 Janice Connor to David Russell and* *16 Manuela Capodanno, correct?* *17 A. That's as good as I would* *18 get.* *19 Q. Yeah, thank you.* *20 It's dated March 6, 2012.* *21 Fair?* *22 A. Yes, it is.* *md122914, (Pages 227:11 to 230:12)* *227* *11 This was almost exactly a* *12 month before the abstract regarding the* *13 Pinnacle retrospective study was* *14 submitted, correct?* *15 A. Correct.* *16 Q. And here, Janice Connor* *17 writes, "Hi David. The attached Prolift* *18 study is probably quite similar to what I* *19 would expect a Pinnacle study to sound* *20 like. In general, I thought it may* *21 assist your team as they build the* *22 manuscript."* *23 Did I read that correctly?* *24 A. You did, yeah.* *228* *1 Q. Doctor, are you part of* *2 David's team, as he refers to in this* *3 e-mail, for building the Pinnacle* *4 manuscript?* *5 A. No.*

		Q. And if we look at the attachment, under "Study Design," we see that this is a -- a retrospective study, correct? *A. Yes.* *Q. And your study was a retrospective study, correct?* *A. Correct.* *Q. And if we look at the conclusion, it says, "Rates of mesh complications and prolapse recurrence are relatively low in an experienced team."* *Did I read that correctly?* *A. So where are you --* *Q. Under the "Conclusion" section of the attachment.* *A. Yes.* *Q. What was the conclusion of your retrospective review of the* *229* *Pinnacle?* *A. Should I just read it word for word for you?* *Q. Sure.* *A. "The incidence of device and procedure-related complications following pelvic organ prolapse repair using the Pinnacle PFR kit was 12.7 percent. The incidence of mesh" -- "mesh exposure requiring surgical intervention was*

		4.2 percent." *Should I keep going?* *Q. Is there anything else?* *A. "The global incidence of surgical reoperation following repair with the Pinnacle PFR kit was 5.2 percent. No patients underwent reoperation for prolapse; thus, in this retrospective study, long-term results support the safety and effectiveness of the Pinnacle PFR kit with low mesh exposure and no documentation of patient complaint of recurrent prolapse."* *Q. Can we agree that the* *230* *conclusion reached in your paper is fairly similar to the conclusion reached in the Landsheere paper that Janice Connor forwarded to David Russell prior to the submission of your paper in the AUGS journal?* *A. Well, we --* *MR. SODEN: Object to the form of the question.* *THE WITNESS: We seem to have more far-reaching conclusions.* *md122914, (Pages 233:12 to 234:3)*

		233 *12 Q. Doctor, is the conclusion* *13 that you reached similar to the* *14 conclusion reached in the study that* *15 Janice Connor forwarded to David Russell?* *16 MR. SODEN: Object to the* *17 form of the question.* *18 THE WITNESS: As I just* *19 answered, we have more* *20 far-reaching conclusions. We* *21 don't have the exact same* *22 percentage amounts.* *23 But the global idea that* *24 there's low mesh exposure and low* *234* *1 recurrence, thankfully, is very* *2 similar because they're both using* *3 mesh to fix the same thing.* *md122914, (Pages 240:9 to 241:6)* *240* *9 Q. Let's mark Exhibit 20.* *10 Does this document look* *11 familiar to you?* *12 A. I'm not sure. You know,* *13 it's another e-mail.* *14 Q. Okay. It's from Janice* *15 Connor to Lori Nesbitt and David Russell,* *16 correct?* *17 A. Correct.*

		18 Q. Dated September 26, 2012? *19 A. Correct.* *20 Q. And it's entitled, "Pinnacle* *21 Manuscript," correct?* *22 A. Correct.* *23 Q. Here, Janice writes, "Hi,* *24 Lori. Please see the attached manuscript* *241* *1 with BSC edits. I included* *2 comments/questions within the document as* *3 well, but I would be interested in your* *4 feedback."* *5 Did I read that correctly?* *6 A. Yes.* *md122914, (Page 258:3 to 258:6)* *258* *3 Q. Did this manuscript that we* *4 see in Exhibits 22, 21, was that* *5 published in the journal?* *6 A. No, it hasn't.*
jc042115, (Pages 564:23 to 567:18) **564** **23 (Exhibit 1344 marked for** **24 identification)** **25 Q. (By Mr. Anielak) Now I want to talk** **565** **1 about Uphold.** **2 And, I've marked as deposition** **3 Exhibit 1344 a summary of the clinical trials of** **4 Uphold?** **5 A. Yes.** **6 Q. And, how many clinical studies have** **7 been done with Uphold?** **8 A. 16.** **9 Q. Okay. And, in terms of the number** **10 of women.**	**564:23-567:18 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**

How many women have received Uphold as part of those studies? A. It's been over 800. Q. And, how long have patients been followed in this particular study? A. In these studies it ranges from one month to over two and a half years. Q. And, we talked about the investigators in the studies. Again, describe for the jury what an investigator does. A. An investigator is the physician who treats the patients, follows the patients, and collects the data. So, it's a research physician. 566 Q. And, in looking at all of the Uphold studies, what do the Uphold studies show in terms of the effectiveness of Uphold in treating patients? A. It shows that it's effective. It works. So, from -- and why I can say that is the effectiveness is assessed by objective measurements. So, again, the anatomy, where is that pelvic organ prolapse at. Is it better than it was before surgery. So, that's from the objective standpoint. And the studies also show from the patients standpoint their reports of symptoms that were due to their pelvic organ prolapse are improved significantly. So, before surgery to after surgery, those symptoms are significantly improved. Q. And, do the studies also look at the safety of the Uphold device? A. Yes. Q. And, how do they go about doing that? A. So, I ask the physician questions that during the physical exam does he see, feel anything, see if there is anything going on with 567 the patient. Also the patients are reporting		

3 events to the physician. So, if the patient 4 reports pain, exposure, if they're aware of it, 5 they report that to the physician, the physician 6 reports it in the studies, and it gets published 7 in these papers. So, we can tell by looking at 8 all these papers that the reports that are coming 9 in on the product in the studies is within a 10 range for what we know is to be expected. There 11 aren't any trends or significant variations in 12 reports or any adverse events that have not been 13 reported before. And they're similar to other 14 products that are on the market. 15 Q. And, in terms of the clinical 16 studies that have been done on Uphold, do they 17 support the safety of the device? 18 A. They do.		
jc042115, (Pages 567:22 to 568:1) 567 22 (Exhibit 1345 marked for 23 identification) 24 Q. (By Mr. Anielak) I want to talk 25 about one of the clinical studies that have been 568 1 done with the Uphold device.	567:22-568:1 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any. 568:9-	Plaintiffs adopt and incorporate their counter designations, if any.
jc042115, (Pages 568:9 to 569:19) 568 9 So, this particular study is what? 10 Explain this to the jury. 11 A. There is a study by Dr. Jirschele 12 and other authors published in the International 13 Urogynecology Journal in 2014 titled a 14 Multicenter Prospective Trial to Evaluate 15 Mesh-Augmented Sacrospinous Hysteropexy for 16 Uterovaginal Prolapse. 17 Q. Okay. So, this was a study 18 published in November of 2014? 19 A. Correct.	568:9 - 569:19 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

20 Q. And it was on Uphold? 21 A. That is correct. 22 Q. And, explain to the jury what that 23 means when it's a prospective mesh-augmented 24 sacrospinous. Explain what that means. 25 A. Yup, it's a great title. So, 569 1 multicenter means it's more than one hospital. 2 Prospective means patients are treated today, for 3 example, and followed forward. It's assessing 4 mesh-augmented sacrospinous hysteropexy, means 5 it's the use of mesh, the Uphold device, 6 supporting the suspension of the uterus for a 7 uterovaginal prolapse. 8 So, sacrospinous hysteropexy means 9 you're basically supporting the uterus for 10 prolapse. 11 Q. Okay. And, this particular study. 12 Was it funded by Boston Scientific? 13 A. It was. 14 Q. So, this was part of the ISR 15 program? 16 A. Yes. 17 Q. And, how many women were part of the 18 study group? 19 A. There were 99.		
jc042115, (Pages 569:23 to 572:13) 569 23 Did the study look at 24 effectiveness? 25 A. It did. So, they report at 12 570 1 months success as measured by a composite 2 outcome. And, I'll explain that. It was 97.7% 3 and then they measured in a little different way, 4 it was 96.6. So -- 5 Q. Yeah. Explain those to the jury. 6 What do those show in terms of the effectiveness 7 of the Uphold device? 8 A. So, basically the physicians are 9 measuring what different points along the vagina 10 where the prolapse is, where the uterus is, 11 basically. So, there is different landmarks, 12 basically, is the way that the community has	569:23-572:13 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

established a grading system.
So, they're saying here that 97.7% of the women were successful if you, basically, said there is certain point in the vagina that if the prolapse is there or above then they'll categorize the patient as successful. So, that was 97.7.
Then they said, well, if there is a different point with the uterus, which is point C, it's higher. If they use that as the landmark, it's 96.6.
So, the reason why they did that was because in the literature there are reports

571

defining success differently. So, they reported it in the different ways that they see in the literature. That way you can compare to different studies.
Q. And, so, did this study support the effectiveness of the Uphold device?
A. Yes.
Q. And, in terms of what the authors concluded, what did they say with regard to whether this particular Uphold was effective in this study?
A. So, they concluded that sacrospinous histeropexy using a minimally invasive polypropylene mesh kit is an effective and safe technique for addressing uterovaginal prolapse as an alternative to hysterectomy at the time of pelvic reconstructive surgery.
Q. So, when they talk about sacrospinous hysteropexy, they're referring to Uphold?
A. Right, using the mesh kit. Yes.
Q. Okay. So, the physicians are reporting that Uphold was effective?
A. Yes.
Q. And, do you agree that that's a

572

reasonable conclusion based on their data?
A. I do, based on their data and how they reported their information and how they --
and the safety and effectiveness results.
Q. Okay. And, then, in terms of

6 complications and safety. 7 Do the physicians also look at 8 safety and complications in this study? 9 A. They did, yes. 10 Q. Did they look at, for example, mesh 11 exposure? 12 A. They did. So, they reported an 13 exposure rate of 6.52%.		
jc042115, (Pages 572:17 to 573:13) 572 17 In terms of the conclusions, the 18 authors concluded that Uphold was safe in this 19 particular study? 20 A. Yes. 21 Q. And, do you believe that that's a 22 reasonable conclusion based on their data? 23 A. I do, yes. 24 Q. And, in terms of the overall studies 25 that have been conducted on Uphold, including the 573 1 Jirschele study, do all of the uphold studies 2 support the safety and effectiveness of the 3 device? 4 A. They do, yes. 5 Q. And, are those studies also looking 6 at similar ways in terms of evaluating 7 effectiveness? 8 A. Yes. So, all the studies report on 9 safety. And they all report on the success of 10 the procedure, which is the effectiveness and 11 where the anatomy landmarks are. So that's that 12 grading system, but also where the patients 13 reports were.	FRE 572:17 – 573:13 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.
jc042115, (Page 577:18 to 577:21) 577 18 What is the expectation of Boston 19 Scientific regarding whether doctors should have 20 an appreciation for the information that's 21 available on the devices?	577:18-577:21 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.	Plaintiffs adopt and incorporate their counter designations, if any.

jc042115, (Pages 577:24 to 578:17) **577** **24 THE WITNESS: In out -- we do have** **25 an expectation.** **578** **1 So, in our directions for use we** **2 actually do indicate that physicians should** **3 read the literature. So, obviously, the** **4 literature gets updated as often as studies** **5 are completed.** **6 These medical journals are monthly** **7 subscriptions. So, each month there is new** **8 studies that are coming out. So, we do** **9 expect physicians to review the literature.** **10 They're implanting the products and they're** **11 using the products so they should have an** **12 understanding.** **13 Q. (By Mr. Anielak) And, is it your** **14 experience that doctors do, in fact, have an** **15 understanding about what the literature says** **16 based on your interaction with doctors at** **17 conferences and other places?**	**577:24-578:17 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**
jc042115, (Pages 578:19 to 579:2) **578** **19 THE WITNESS: Yes, it is. And, the** **20 reason why I answer that yes is when I talk** **21 to the physicians about current research or** **22 ideas on doing research, they know the** **23 studies in their heads. So, they're** **24 actually able to, without anything in front** **25 of them, talk about certain studies that** **579** **1 are published, and what the results showed** **2 in certain study designs.**	**578:19-579:2 BSC has previously designated this testimony. Plaintiffs adopt and incorporate objections set forth in counter designations, if any.**	**Plaintiffs adopt and incorporate their counter designations, if any.**
jc042115, (Page 580:3 to 580:7) **580** **3 Q. And, based on the testing of the** **4 finished mesh, has Boston Scientific concluded** **5 that the Pinnacle and Uphold devices are safe and** **6 effective?** **7 A. Yes.**	**580:3-580:7 FRE 401, 402, 403, 701, 702**	

1. **Objections to Counter Exhibits.**

a. Plaintiffs object to Conner 1328. This exhibit was previously proffered by BSC in their original page/line designations and objected to. Plaintiffs adopt and incorporate the objections identified in their counters to Janice Conner's designated testimony by BSC.

b. Plaintiffs object to Conner 1329. This exhibit was previously proffered by BSC in their original page/line designations and objected to. Plaintiffs adopt and incorporate the objections identified in their counters to Janice Conner's designated testimony by BSC.

c. Plaintiffs object to Conner 1330 under FRE 403. This exhibit was identified in BSC's original designations for Janice Conner.

d. Plaintiffs object to Conner 1339. This exhibit was previously proffered by BSC in their original page/line designations and objected to. Plaintiffs adopt and incorporate the objections identified in their counters to Janice Conner's designated testimony by BSC.

e. Plaintiffs object to Conner 1344. This exhibit was previously proffered by BSC in their original page/line designations and objected to. Plaintiffs adopt and incorporate the objections identified in their counters to Janice Conner's designated testimony by BSC.

f. Plaintiffs object to Conner 1345 under FRE 403. This exhibit was identified in BSC's original designations for Janice Conner.

g. Plaintiffs object to Conner 1337 under FRE 403.

h. Plaintiffs object to Conner 1338 under FRE 403.

i. Plaintiffs object to Conner 1340 as the exhibit lacks proper foundation. Plaintiffs cannot discern which studies were included/excluded. Additionally, Plaintiffs object under FRE 1006 as BSC has not produced or identified the underlying source materials being presented through the exhibit.

j. Plaintiffs object to Conner 1341 as the exhibit lacks proper foundation. Plaintiffs cannot discern which studies were included/excluded. Additionally, Plaintiffs object under FRE 1006 as BSC has not produced or identified the underlying source materials being presented through the exhibit.

2. Counter Exhibits to Counter Exhibits

a. Connor 1352
b. Daives 14
c. Daives 17
d. Daives 18
e. Daives 20
f. Davies 21
g. Plaintiffs adopt and incorporate the exhibits identified in their counter designations regarding this witness and testimony.

DATED: July 20, 2015

Respectfully Submitted,

TRACEY & FOX LAW FIRM

/s/ Sean Tracey
Sean Patrick Tracey
State Bar No. 20176500
Shawn P. Fox
State Bar No. 24040926
Clint Casperson
State Bar No. 24075561
440 Louisiana, Suite 1901
Houston, TX 77002
(800) 925-7216
(866) 709-2333
stracey@traceylawfirm.com
sfox@traceylawfirm.com
ccasperson@traceylawfirm.com

/s/ *John R. Fabry*
John R. Fabry
Texas Bar No. 06768480
Mark R. Mueller
Texas Bar No. 14623500
MUELLER LAW, PLLC
404 West 7th Street
Austin, TX 78701
(512) 478-1236
(512) 478-1473 (Facsimile)
John.Fabry@muellerlaw.com
Mark@muellerlaw.com
Meshservice@muellerlaw.com

CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

TRACEY & FOX LAW FIRM

/s/ Sean Tracey
Sean Patrick Tracey
State Bar No. 2176500
Shawn P. Fox
Clint Casperson
State Bar No. 24075561
State Bar No. 24040926
440 Louisiana, Suite 1901
Houston, TX 77002
(800) 925-7216
(866) 709-2333
stracey@traceylawfirm.com
sfox@traceylawfirm.com
ccasperson@traceylawfirm.com

/s/ *John R. Fabry*
John R. Fabry
Texas Bar No. 06768480
Mark R. Mueller
Texas Bar No. 14623500
MUELLER LAW, PLLC
404 West 7th Street
Austin, TX 78701
(512) 478-1236
(512) 478-1473 (Facsimile)
John.Fabry@muellerlaw.com
Mark@muellerlaw.com
Meshservice@muellerlaw.com